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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

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Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of the SAMHSA PDMP Electronic Health Record (EHR) Integration and Interoperability Expansion Program - New - National Center for Injury Prevention and Control (NCIPC), Center for Disease Control and Prevention (CDC).

Background and Brief Description

In 2009, drug overdose deaths became the leading cause of injury death in the United States (U.S.), exceeding motor vehicle traffic crash deaths for the first time, a trend that continued in 2010. Prescription drugs, particularly opioid pain relievers, have been identified as the main driver of this increase. The number of overdose deaths per year involving opioid pain relievers increased more than four-fold from 1999 to 2010 (from 4,030 to 16,651), outnumbering overdose deaths involving all illicit drugs combined. Morbidity associated with opioid pain reliever abuse increased in parallel. The rate of emergency department visits associated with the misuse or abuse use of

opioid pain relievers increased 153% from 2004 to 2011, while rates for illicit drugs remained largely stable.

Concurrent to this rise in overdose death rates, the sales of opioid pain relievers have increased four-fold since 1999. According to the National Survey of Drug Use and Health, the primary source of prescription drugs for non-medical use is from prescribed and dispensed prescriptions; more than 70% of those who reported non-medical use of pain relievers said they obtained the pain reliever they most recently used from a friend or relative. Moreover, multiple studies have found an association between increased opioid prescribing - in the amount prescribed per prescription, the total days' supply, and the number of prescriptions per patient - and increased morbidity and mortality in the U.S. over the last 10 to 15 years.

Prescription Drug Monitoring Programs (PDMPs) are now recognized as a key tool in federal, state, and local efforts to address prescription drug abuse and misuse. PDMPs are state databases to which pharmacies and other dispensers report dispensed outpatient controlled substance prescription information. Forty-nine states have passed legislation authorizing a PDMP, and 45 states currently have an operational program. In the vast majority of these programs, prescribers and pharmacists (herein

referred to collectively as providers) can register to become an authorized user of the PDMP. Following authorization, users can then conduct online queries to obtain prescription histories for their patients, a process that may take up to several minutes. For many providers, accessing patient prescription histories offers critical input that can inform their clinical decision-making. This process has shown promise in preventing prescribing to patients who appear to be abusing prescription medications or obtaining controlled substances prescribed by multiple providers without knowledge of the other prescriptions (referred as doctor shopping) while enabling appropriate prescribing and dispensing for legitimate patients, especially for pain medication.

However, for many providers, even the few minutes required to log on to the PDMP and query a patient's prescription history present a barrier to regular use. Moreover, gaps in patients' prescription histories due to limited interstate sharing of PDMP data has contributed to relatively slow rates of provider registration with and use of PDMPs. PDMP reports show that it often takes four or more years following the implementation of online PDMP access for registration in the state to reach 50% of the prescribers who write controlled substance prescriptions, thus limiting the potential impact of these programs. Various strategies have been proposed to increase provider use of PDMPs.

For example, several states have recently passed legislation mandating provider registration with and use of the PDMP under certain circumstances. Many states have also initiated efforts to enroll providers in educational training programs on the value of using PDMP data to counteract the prescription drug overdose epidemic. The project described below takes a different approach to increasing provider use of PDMPs.

In an effort to increase provider utilization of PDMPs and to effectively reduce prescription drug abuse and overdose, the Substance Abuse and Mental Health Services Administration (SAMHSA) funded projects in nine states beginning in fiscal year (FY) 2012 and lasting for a period of two years through its PDMP Electronic Health Records (EHRs) Integration and Interoperability Expansion (PEHRIIE) cooperative agreement program. The goals of this program are to:

- 1) Increase provider utilization of their state's PDMP by improving real-time access to PDMPs via the integration of PDMP data and/or access thereof within health information technologies (HIT) such as health information exchanges (HIEs), EHR systems, and/or pharmacy dispensing software (PDS). Ultimately, when providers access a patient's EHR, s/he will have automatic access to that patient's up-to-

date prescription history within the course of their normal clinical workflow, thereby obviating the time and effort otherwise needed to access the PDMP and obtain this information separately from the patient's medical record. Similarly, when a pharmacist calls up patient information via the PDS, the patient's prescription history from the PDMP will be automatically compiled, allowing for expedited access and review prior to dispensing.

- 2) Increase provider utilization of PDMP data by increasing the comprehensiveness and quality of PDMP data by increasing the interoperability of PDMPs across state lines. When providers access a patient's prescription history from his or her state PDMP (either directly or via the systems described above), data from other state PDMPs with which the home state PDMP is interoperable will be automatically included. By providing a more complete prescription history, PDMP data is expected to have greater utility in clinical decision-making, thus offering an inducement for providers to access and utilize PDMP data more frequently.

Both of these goals are expected to contribute to improving prescribing and dispensing practices, resulting in decreased

prescription drug abuse and misuse and related health consequences such as fatal and non-fatal overdoses as well as lead to improvements in care.

Under the cooperative agreements issued by SAMHSA, the CDC is responsible for conducting a comprehensive process and outcomes evaluation of the PEHRIIE program. The evaluation team consists of health scientists on the Prescription Drug Overdose team within the Division of Unintentional Injury Prevention, National Center for Injury Control and Prevention at CDC, and two subject matter experts at the PDMP Center of Excellence at Brandeis University. The primary goals of the qualitative evaluation component of this work are:

- 1) To understand the processes, challenges, and successes in implementing and sustaining integration of PDMP data with Health Information Technology (HIT) systems and interoperability of PDMP systems across states; and
- 2) To understand the experiences of clinical end users with the systems being upgraded under the PEHRIIE program and to capture their recommendations, if any, for how the goals of the PEHRIIE could have been better accomplished.

To achieve these evaluation goals, the CDC evaluation team will conduct qualitative interviews with those individuals involved in the planning and implementation of the PEHRIIE projects (i.e., key project staff and stakeholders) as well as with the clinical end users (i.e., prescribers and pharmacists) of the PDMPs in the states where these projects are taking place.

This evaluation is consistent with CDC's strategic goals of improving surveillance, informing policy, and improving clinical practice. CDC believes that the most effective interventions in combating the prescription drug overdose epidemic include those designed to identify and address high-risk patients at a stage when their risky behaviors can be most effectively addressed. Strong yet accessible PDMPs that promote proactive patient interventions are a critical component of this high-risk focused strategy. By enabling providers to identify high-risk patients at the point of care, via improved access to and use of PDMPs and improved comprehensiveness of PDMP data, providers can intervene with patients and address their high-risk behaviors, including providing or redirecting patients to substance abuse treatment as necessary. Through this evaluation, CDC will better understand the impact of PDMP integration and interoperability in the funded states.

The total annual estimated burden hours for the planned qualitative information collection are 235 hours. Total burden time includes the time to conduct interviews with key project staff/stakeholders and clinical end users, and the time spent by recruiters at the PEHRIIE implementation sites to identify potential clinical end user interviewees.

It will take 79 hours of interviewee time to complete all of the key project staff/stakeholder interviews necessary for the planned evaluation of the PEHRIIE program. Interviews will be conducted with 91 key project staff members/stakeholders across the nine PEHRIIE-funded states (range: 6 - 16 interviews per state) as well as 14 key project staff/stakeholders representing five companies working with multiples states involved in the PEHRIIE program, for a total of 105 key project staff/stakeholders interviewees. Based on pilot testing with three individuals, each key project staff/stakeholder interview will take approximately 45 minutes to complete. Therefore, 105 key project staff/stakeholder interviews at 45 minutes each will require 79 hours of interviewee time.

It will take 117 hours of interviewee time to complete all of the clinical end user interviews necessary for the planned evaluation of the PEHRIIE program. Each interviewee will be

interviewed once. End user interviews will be conducted at 39 implementation sites distributed across all nine PEHRIIE states (range: 3 - 8 sites per state). Interviews will be conducted with three clinical end users per implementation site for a total of 117 clinical end user interviews. Based on pilot testing with three individuals, each clinical end user interview will take one hour to complete. Therefore, 117 clinical end users at 1 hour each will require 117 hours of interviewee time.

It will take 39 hours of recruiter time to identify potential clinical end user interviewees, to collect the contact information from these clinical end users, and to disseminate this collected information to the CDC evaluation time. The CDC will work with one recruiter per implementation site to complete these tasks. Based on the time required to complete similar tasks during the planning of the clinical end user pilot interviews, each recruiter is expected to spend approximately one hour on these tasks. Therefore, 39 recruiters spending one hour each on this information collection will require 39 hours of recruiter time.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Avg. Burden per Response (in hrs)	Total Burden (in hrs)
Key Project Staff/ Stakeholders	Key Project Staff/ Stakeholders Interview Guide	105	1	45/60	79
Clinical End Users	Clinical End Users Interview Guide	117	1	1	117
Clinical End User Recruiters	N/A	39	1	1	39
	Total				235

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